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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,452	05/05/2006	Hengyuan Lang	34056-US-PCT	9887
75/074 75/90 07/29/2009 NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC. 220 MASSACHUSETTS AVENUE CAMBRIDGE, MA 02139				
EXAMINER WILLIS, DOUGLAS M				
ART UNIT		PAPER NUMBER		
1624				
MAIL DATE		DELIVERY MODE		
07/29/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/565,452

**Applicant(s)**

LANG ET AL.

**Examiner**

DOUGLAS M. WILLIS

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, 5, 12, 20, 21, 23, 29, 34-37 and 54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 12, 20, 21, 23, 29, 34-36 and 54 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Status of the Claims / Priority*

Upon further consideration, the finality of the *Final Rejection*, mailed on April 14, 2009, is hereby withdrawn.

Claims 1, 3, 5, 12, 20, 21, 23, 29, 34-37 and 54 are pending in the current application. According to the *Amendments to the Claims*, filed July 13, 2009, claims 1 and 23 were amended and claims 2, 4, 6-11, 13-19, 22, 24-28, 30-33, 38-53 and 55-61 were cancelled. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/US2004/023726, filed July 23, 2004, which claims priority under 35 U.S.C. § 119(e) to US Provisional Application No. 60/490,096, filed July 25, 2003.

### *Status of Restrictions / Election of Species*

Applicant's affirmation of the following election, without traverse, in the reply filed on



March 5, 2009, is acknowledged: Group II - claims 1, 3, 5, 12, 20, 21, 23, 29, 34-37 and 54, where Y = -L-R<sup>3</sup>, wherein L = -C(=O)NH- or -NH(C=O)-; and X = -phenyl, -pyridinyl or -pyrimidinyl; and b) substituted benzene of formula (I) - p.

33, example 1.

The requirement was made FINAL in the *Final Rejection*, mailed on April 14, 2009.

The sections of U.S.C. Title 35 that formed the basis of prior rejections formulated, as well as any references supporting said rejections, that are not included with this Office action, may be found in either the *Non-Final Rejection*, mailed on December 5, 2008, or the *Final Rejection*, mailed on April 14, 2009. Furthermore, any rejections or objections of record not

explicitly addressed herein below, are hereby withdrawn, in light of applicant's arguments and/or the *Amendments to the Claims*, filed July 13, 2009.

Thus, a second Office action and prosecution on the merits of claims 1, 3, 5, 12, 20, 21, 23, 29, 34-37 and 54 is contained within.

### ***New Claim Objections***

Claim 34 is objected to because of the following informalities: the status identifier is misspelled. Appropriate correction is required.

Claim 37 is objected to because of the following informalities: *carboxyamide* should be replaced with *carboxamide*. Appropriate correction is required.

### ***New Claim Rejections - 35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5, 12, 20, 21, 23, 29, 34-36 and 54 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase *(optionally) substituted*, in claim 1, is a relative phrase which renders the claim indefinite. The phrase *(optionally) substituted* is not defined by the claim, the specification does not provide an adequate standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification, on page 5, defines the phrase *(optionally) substituted* using *substituted* and a laundry list of exemplary substituents, but fails to explicitly limit the invention to any specifically disclosed

embodiments. Consequently, the *substituted* benzenes and pharmaceutical compositions of the formula (I) have been rendered indefinite by the use of the phrase *(optionally) substituted*.

The examiner suggests removal of the phrase *(optionally) substituted* and providing discrete substituents for each occurrence where substituents are desired, to overcome this rejection.

#### ***Allowable Subject Matter***

No claims are allowed.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS, whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Thursday from 8:00-6:00 EST. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DOUGLAS M WILLIS/  
Examiner, Art Unit 1624

/James O. Wilson/  
Supervisory Patent Examiner, AU 1624